Heritage Information Systems, Inc.

SmartPA

Clinical Edit Criteria Proposal

Drug/Drug Class:	**5HT3 Receptor Antagonists**
Date:	**October 6, 2004**
Prepared for:	
Prepared by:	Missouri Medicaid

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose:

Control pharmacy program costs by limiting the use of the 5HT3 receptor antagonists as first-line agents in the prevention of nausea and vomiting except when associated with cancer therapy.

Why was this Issue Selected:

The 5HT3 receptor antagonists are indicated for the prevention and treatment of nausea and vomiting associated with chemotherapy and radiotherapy; and for the care of acute nausea and vomiting following surgery. The exception within this therapeutic class is Lotronex® (alosetron), which is indicated for the treatment of severe diarrhea associated with irritable bowel syndrome. The management of chemotherapy-induced nausea and vomiting is a critical aspect of treating cancer patients. The advent of agents within this therapeutic class was a significant breakthrough for the practice of oncology. However, because of the increased cost of these products, it is essential that therapy be appropriately monitored, and prudently utilized for the right patient population. The average 5HT3 prescription costs the program $567.86, while the average cost for a Compazine prescription is $24.36.

Program-specific information:

Drug	Claims	Expense
• Alosetron (Lotronex®)	*54*	*$9,210*
• Dolasetron (Anzemet®)	*592*	*$175,765*
• Granisetron (Kytril®)	*547*	*$304,984*
• Ondansetron (Zofran®)	*8,319*	*$4,911,483*
• Palmosetron (Aloxi®)	*0*	*$0*
	(FY2003)	

Setting & Population:

Medicaid fee-for-service patients receiving chemotherapy and/or radiotherapy.

Type of Criteria:	☐ **Increased risk of ADE**	☐ **Non-Preferred Agent**
	☒ **Appropriate Indications**	☐
Data Sources:	☐ **Only administrative databases**	☒ **Databases + Prescriber-supplied**

Setting & Population

- Drug/drug class for review: 5HT3 Receptor Antagonists
- Age range: All patients receiving chemotherapy and/or radiotherapy
- Gender: males and females

Approval Criteria

Approval Diagnoses

Condition	Submitted ICD-9 Diagnoses/CPT Procedure Codes	Inferred Drugs	Historical Date Range	Client Approval (Initials)
Cancer	140 - 239		2 years	
Cancer (inferred)	-----	Antineoplastics	2 years	

- History of chemotherapy and/or radiotherapy
- IBS with severe diarrhea as primary bowel symptom (Lotronex®-only)
  - Female

Denial Criteria

- Therapy will be denied if no approval criteria are met.

Required Documentation

Laboratory results: ☐
MedWatch form: ☐

Progress notes: ☐

Disposition of Edit

- **Denial:** Exception Code "682" (Clinical Edit)

References

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2003.
2. USPDI, Micromedex, 2004.
3. Facts and Comparisons, pg. 869 – 873b; 2004.